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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,412	03/20/2002	Herbert Markl	02481.1781	5276

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EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/088,412

Applicant(s)

MARKL ET AL.

Examiner

David M. Naff

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-92 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-92 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/2/02.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1651

DETAILED ACTION

A preliminary amendment of 3/20/02 canceled claims 1-38, and added new claims 39-92.

Claims examined on the merits are 39-92, which are all claims in
5 the application.

Specification

The disclosure is objected to because of the following informalities: the specification fails to contain headings designating different sections.

10 The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

15 The following order or arrangement is preferred in framing the specification and, except for the reference to the drawings, each of the lettered items should appear in upper case, without underling or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- 20
- (a) Title of the Invention.
 - (b) Cross-Reference to Related Applications.
 - (c) Statement Regarding Federally Sponsored Research or Development.
 - 25 (d) Reference to a "Sequence Listing," a table, or a computer program listing appendix submitted on compact disc (see 37 CFR 1.52(e) (5)).
 - (e) Background of the Invention.
 - 1. Field of the Invention.
 - 30 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
 - (f) Brief Summary of the Invention.
 - (g) Brief Description of the Several Views of the Drawing(s).
 - (h) Detailed Description of the Invention.
 - 35 (i) Claim or Claims (commencing on a separate sheet).
 - (j) Abstract of the Disclosure (commencing on a separate sheet).

Art Unit: 1651

(k) Drawings.

(l) Sequence Listing, if on paper (see 37 CFR 1.821-1.825).

The following suggestions are made.

Page 1,

5 above the first line below the title insert --

BACKGROUND OF THE INVENTION

1. Field of the Invention

--.

between lines 11 and 13 insert --

10 2. Description of the Related Art

--.

page 2, between lines 35 and 37 insert --

SUMMARY OF THE INVENTION

--.

15 page 10, between lines 32 and 34 insert --

BRIEF DESCRIPTION OF THE DRAWINGS

--.

page 11, between lines 6 and 8 insert --

DETAILED DESCRIPTION OF THE INVENTION

20 --.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C.

112:

25 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact

Art Unit: 1651

terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5 Claims 70-80 and 82-92 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a reaction system as required by claim 82 when requiring the membrane module of claim 83 and gas supply means is provided for both the culture vessel and the space of the module containing culture fluid,
10 does not reasonably provide enablement for a different reaction system and for a module not being in a reaction system as required by claim 70. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

15 The specification (page 3, lines 9-27) indicates that a reaction system as set forth above is required. The claims must be commensurate in scope with the specification.

Claim Rejections - 35 USC § 112

20 The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

25 Claims 50, 51, 61 and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1651

In line 2 of claim 50, the structure of a plate module is uncertain and it is not clear how a plate module differs from a membrane module. Furthermore, if the plate module is a structure not containing a membrane such that a membrane module is no longer used, claim 39 does not permit substituting a non-membrane module for the membrane module. While the structure of a device may be further limited in a dependent claim, the dependent claim cannot remove structure of a preceding claim and substitute different structure. Such substitution requires an independent claim drawn to the structure that results from substituting structure.

In line 2 of claim 51, requiring a dialysis membrane is confusing since claim 39 already requires a dialysis membrane.

In line 2 of claim 61 and line 3 of claim 62, "from the group comprising" should be changed to --- selected from the group consisting of --- for a proper Markush group.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly

Art Unit: 1651

owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 39-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Portner et al (listed on form PTO-1449).

The claims are drawn to a method for culturing cells using a reaction system and to a reaction system for carrying out the method wherein the reactions system contains a container for dialysis fluid and a culture vessel for culturing cells and a membrane module in fluid communication with the container and vessel. The module contains two spaces separated by a dialysis membrane. Dialysis fluid is circulated through one of the two spaces and culture fluid is circulated through the other space. A first gas is introduced into the vessel for culturing cells, and a second gas is introduced into culture fluid in the membrane module. Also claimed is the membrane module alone with a gas supply means to supply gas to one of the spaces.

Portner et al disclose (Figure 2a, page 405) a reaction system as required by the present claims except for supplying gas to culture fluid in the dialysis module (membrane module). Portner et al disclose (page 404, right col, 3rd complete paragraph) that when cells

Art Unit: 1651

are pumped through the external module, the cells can suffer from oxygen limitation. Figure 3a (page 406) discloses a reactor without an external module where a culture chamber is separated from a dialyzing chamber by a dialysis membrane. Air is supplied to the culture chamber. In Figure 3b, air is supplied to the dialyzing chamber.

It would have been obvious to supply air to space containing circulating culture liquid containing cells in the dialysis module of the reactor of Figure 2a of Portner et al to prevent cells from suffering oxygen limitation as disclosed on page 404 since it would have been apparent from Figure 3a that oxygen can be supplied to cells in a chamber separated from a dialyzing chamber by a dialysis membrane. The conditions of dependent claims not disclosed by Portner et al are conditions that would be expected to require control when using the reaction system of Portner et al, and such conditions would have been matters of optimization depending on individual preference well within the skill of the art. Providing air to the dialyzing chamber as required by certain claims would have been suggested by Figure 3b of Portner et al.

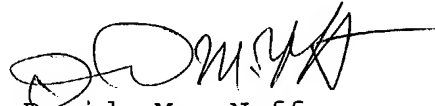
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

Art Unit: 1651

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

5 Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For
10 more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


David M. Naff
Primary Examiner
Art Unit 1651

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DMN
10/1/04